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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,941	08/28/2001	Atsushi Sogabe	211352	6205
23460	7590	01/21/2004	EXAMINER	
LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780			SLOBODYANSKY, ELIZABETH	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,941

Applicant(s)

SOGABE ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6 May, 6 Nov & 22 Dec 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33 and 35-75 is/are pending in the application.
- 4a) Of the above claim(s) 71-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33 and 35-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 6, 2003 has been entered.

The Declaration under 37 CFR 1.132 by Dr. Atsushi Sogabe filed November 6, 2003 has been entered.

The AF amendment filed May 6, 2003 amending the specification to replace pl 3.5 with pl 4.5, amending claims 24, 25, 27, 33 and 35-37 and canceling claims 26, 29, 31, 32 and 34 has been entered. Note that amendment to Tables 3 and 4 has replaced paragraph of column 10 (not 12), line 65 - column 11, line 29.

The amendment filed November 6, 2003 adding claims 43-70 has been entered.

The amendment filed December 22, 2003 canceling claims 24, 25, 27, 28 and 30, amending claims 33, 35-54, 56, 63, 70 and adding claims 71-75 has been entered.

Claims 33 and 35-75 are pending.

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Election/Restriction

Newly submitted claims 71-75 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 71-74 are drawn to a method of making a product, a creatine amidinohydrolase, that is different in scope from a product of the instant invention.

Inventions of claims (33 and 48) and claim 75 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make creatine amidinohydrolase with properties other than claimed. Further, the product as claimed can be made by culturing the microorganism as in methods of claims 38 and 55 or by chemical synthesis.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 71-75 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

The Declaration under 37 CFR 1.132 by Dr. Atsushi Sogabe filed November 6, 2003 is insufficient to overcome the rejections following below. It appears that the text bridging pages 5 and 6 is missing. Thus, it is unclear which statements are signed by Dr. Sogabe. Furthermore, it is unclear on which date it was signed. " '02/03/27" presumably means March 27, 2002.

The Declaration describes the results of re-determination of pI of creatine amidinohydrolases of the instant invention obtained from the deposited plasmids (Declaration, clauses 11, 15, 16 and Figure 1 (Attachment A)). Said experimental results represent a sufficient evidence that creatine amidinohydrolase of the invention has pI 4.5 and not pI 3.5 as claimed in US Patent 6,080,553.

The references referred to in the Declaration teach pI of various creatine amidinohydrolases known in the art and not the creatine amidinohydrolases of the instant invention. Said references have been considered to the extent they are described in the Declaration (clause 17). In order for said references to be considered and printed on the patent, they must be submitted in a separate paper (see 37 CFR 1.98(b) and MPEP § 609).

The amendments filed May 6, 2003, November 6, 2003 and December 22, 2003 propose amendments to the claims that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. For example, brackets and underlining are to be used to reflect the amendment relative to the issued

patent claims. All subject matter being added to an original patent claims must be underlined. Thus, currently pending claims 33 and 35-75 must be underlined. A parenthetical expression "(amended)", "(twice amended)", etc., should follow the original claim number.

Furthermore, the amendment to the specification filed May 6, 2003 does not comply with 37 CFR 1.173 because the title of Table 5 reads "Purification of creatine amidinohydrolase from *Escherichia Coli*" where it appears "Purification of creatine amidinohydrolase from *Escherichia Coli*" is intended.

A supplemental paper correctly amending the reissue application is required.

Oath/Declaration

The reissue oath/declaration filed August 13, 2002 with this application is defective because the error which is relied upon to support the reissue application is not an error upon which a reissue can be based. See 37 CFR 1.175(a)(1) and MPEP § 1414. The Declaration states that "It is belief of the undersigned that the present invention encompasses a creatine amidinohydrolase defined by the physicochemical properties such as action, heat stability, and Km value, but not necessarily isoelectric point. This error and any other (i.e. all errors) were made without any deceptive intent" (page 3). However, all pending claims recite the specific isoelectric point of 4.5 that is different from the isoelectric point of 3.5 recited in the patented claims. The correction of this specific error in the reissue should be addressed in the declaration.

Claims 33 and 35-70 are rejected as being based upon a defective reissue Declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the Declaration is set forth in the discussion above in this Office action.

It is noted that the last most recently submitted Declaration was signed on March 27 and 28, 2002 and filed on August 13, 2002. However, amendments subsequently have been made on May 6, 2003, November 6, 2003 and December 22, 2003. None of said amendments have been accompanied by the Oath/Declaration.

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 33 and 35-70 are rejected as being based upon a defective reissue Declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

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Specification

The amendment filed May 6, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: changes of isoelectric point from pI 3.5 to pI 4.5.

Applicant is required to cancel the new matter in the reply to this Office Action.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

Claim Objections

Claims 48, 49, 51 and 53 are objected to because of the following informalities: the claims must end with a period.

Claim 56 is objected to because of the following informalities: the proper recitation of Markush group requires "and" after "(FERM BP-5375)" on line 3.

Appropriate correction is required.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33 and 35-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to add the characteristic of pl 4.5.

Applicants filed the Declaration under 37 CFR 1.132 providing the evidence that creatine amidinohydrolase of the invention has pl 4.5 and not pl 3.5 as claimed in US Patent 6,080,553, *supra*. Because said Declaration is defective in form, as explained above, such amendment introduces new matter.

The Examiner is unable to locate adequate support in the specification for pl 4.5 as originally filed. Without the effective Declaration there is no indication that creatine amidinohydrolase with pl 4.5 was within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter or provide the effective Declaration in the response to this Office Action.

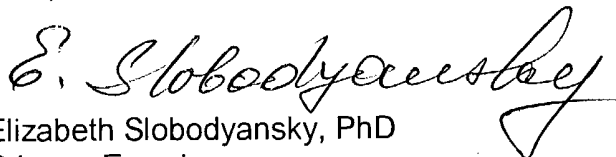
Claims 33 and 35-70 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows: isoelectric point of pl 4.5.

The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner

January 15, 2004